K032056

FEB 2 0 2004

16.0 510(k) Summary

Submitter's Name:	Sunrise Medical HHG, Inc. Respiratory Products Division 100 DeVilbiss Drive Somerset PA 15501
Contact Person:	Stephen F. Krepelka Phone: 814-443-7671 Fax: 814-443-7571 Email: steve.krepelka@sunmed.com
Date Prepared:	July 1, 2003
Device Name:	Bilevel CPAP
Common or Usual Name:	Bilevel Nasal CPAP with Remote Control Module and Analog Breakout Box
DeVilbiss Model Number:	Model 9055
Trade Proprietary Name:	DeVilbiss Bilevel CPAP with Remote Control Module and Analog Breakout Box
Established Registration Number:	2515872
Classification Panel:	Anesthesiology
FDA Classification:	Class II
CFR Section:	868.5905
Product Code:	BZD

Legally Marketed Predicate Devices:

Device Name	**510(k) Notification**
DeVilbiss Model 7355 Bilevel CPAP with Remote Control Module	K952491
Resmed Sullivan VPAP II	K961783
DeVilbiss 9001 Series CPAP	K011229

Description of Device:

The new DeVilbiss Model 9055 Bilevel CPAP is an AC powered, dual-pressure blower designed to be used in providing CPAP therapy to the spontaneously breathing adult patient population with Obstructive Sleep Apnea. Rapid changes in pressure between EPAP (Expiratory Positive Airway Pressure) and IPAP (Inspiratory Positive Airway Pressure) will be achieved by changing the operating speed of the blower.

The bilevel device will have two primary prescription settings: IPAP pressure and EPAP pressure.

Electrical power is supplied to the unit using an AC line cord (100 – 240 VAC, 50/60Hz, 400 Hz). The AC input voltage is converted to a DC voltage by an internal switch-mode power supply. The DC voltage is used to power the internal electronics of the product (microcontroller, motor control circuitry, blower, LCD display, etc.). Positive pressure is produced by spinning a reverse-curved impeller with a brushless DC motor. Room air is drawn into the blower through a filter, pressurized in the blower, and then discharged through a 22 mm ID tube.

Statement of Intended Use:

The DeVilbiss Model 9055 Bilevel CPAP is intended for use in treating OSA in spontaneously breathing adult patients by means of application of positive air pressure. The device is to be used in home and clinical environments.

Statement of Safety and Effectiveness:

The DeVilbiss Model 9055 Bilevel CPAP is equivalent in both function and indications for use to the DeVilbiss Model 7355 and Resmed Sullivan VPAP II Bilevel CPAP legally marketed predicate devices. Displays and constructional details are equivalent to the DeVilbiss Model 9001 CPAP.

The DeVilbiss Model 9055 Bilevel CPAP is designed for use on the order of a physician for the treatment of Obstructive Sleep Apnea. The compressor is constructed of materials, both metal and plastic, that are similar or identical to legally marketed devices. The unit is designed and manufactured to comply with electrical and mechanical safety standards applicable to this type of device.

The new dual pressure level CPAP is designed to provide rapid changes in air pressure between EPAP (expiratory positive airway pressure) and IPAP (inspiratory positive airway pressure). The method of making this pressure change and other characteristics of the Model 9055 Bilevel CPAP are substantially equivalent to other legally marketed devices.

Technological Characteristics:

The DeVilbiss Model 9055 Bilevel CPAP is equivalent in functional characteristics to the existing legally marketed predicate devices. The devices all utilize a microprocessor controlled system to provide a range of dual pressures (IPAP and EPAP) for the treatment of Obstructive Sleep Apnea. All of the devices are tested and approved to recognized agency safety standards. No new technologies have been introduced in the Model 9055 Bilevel CPAP device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Mr. Stephen F. Krepelkea
Project Engineer
Sunrise Medical
100 DeVilbiss Drive
Somersrt, Pennsylvania 15501-2125

Re: K032056
Trade/Device Name: DeVilbiss Model 9055 Bilevel CPAP
Regulation Number: 868-5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 5, 2004
Received: February 6, 2004

Dear Mr. Krepelka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

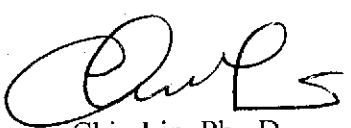
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032056

Device Name: DeVilbiss Model 9055 Bilevel CPAP

Indications For Use: The Model 9055 Bilevel CPAP is intended for use in treating obstructive sleep apnea in adult patients.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032056

Prescription Use Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)